Methods for Submitting Supplemental Files

When submitting supplemental data with an electronic submission, there are two ways in which the files can be associated with the submission; 1) attaching directly to the PDF copy of the study report or, 2) saving on the CD as stand-alone files. Depending on the software used to create the PDFs and CDs along with the quantity of the files, one method may be more advantageous than the other. Additionally, both methods may be used together if circumstances require. In either case, please annotate the study report as clearly as possible to indicate that the supplemental data file(s) exist and where these file(s) can be located (attached to study, on disk, or both). When possible, make these annotations clearly on the front page of the PDF study or alternately on a separate page inserted immediately following the first page. Add a bookmark to this second page. It is understood that these embellishments when added to the PDF of the study and not the paper copy do not violate the *Certification with Respect to Data Integrity* form required of all electronic submissions.

1. Attachment to PDF using Adobe® Acrobat®:

Using the *File Attachment Tool* available on the *Commenting Toolbar* attach the supplemental data file(s) onto the PDF of the study report. This will place a push pin icon onto the page of the PDF. This icon, as with all of the commenting features of Adobe Acrobat, may be relocated on the page by dragging with the mouse. Use the *Free Text Tool* (also on the Commenting Toolbar) to create a short text descriptor adjacent to the push pin icon (see example 1 below.)

2. Stand-alone file on CD:

Copy each supplemental file onto the CD in the same folder as that of the parent study report. Preface each file name with the 8 digit MRID of the associated study followed by a short descriptive name. Use the 3 letter suffix appropriate for the file format. For example "45612301_organwt.xpt". Using the *Free Text Tool* located on the *Commenting Toolbar* of Adobe Acrobat, place an indicator that supplemental files exist on the CD (see example 2 below.) If this feature is unavailable (for example due to the use of software other than Adobe Acrobat), please insert a page immediately after the first page indicating the existence of the supplemental files. Add a bookmark for this page.

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